APR 27 2012

510(k) Summary
Medartis AG
APTUS® Proximal Humerus System
K120108

April 26, 2012

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	APTUS® Proximal Humerus System
Common Name:	Plate, fixation, bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Classification Regulation:	21 CFR 888.3030, Class II
Product Code:	HRS
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

APTUS® Proximal Humerus System is indicated for fractures, osteotomies and non-unions of the proximal humerus.

DEVICE DESCRIPTION

APTUS Proximal Humerus System consists of titanium locking plates, locking and non-locking titanium screws, spiral blades left/ right and the corresponding screws for the spiral blades. The plates are used with TriLock locking screws and cortical screws. APTUS Proximal Humerus plates and spiral blades are made of commercially pure titanium, grade 4, conforming to ASTM F67. TriLock locking and cortical screws are made of titanium alloy conforming to ASTM F136.

EQUIVALENCE TO MARKETED DEVICE

APTUS® Proximal Humerus System is substantially equivalent in indications and design principles to the following legally marketed predicate devices, each of which has been determined by FDA to be substantially equivalent to a legally marketed predicate device:

Synthes (USA), Synthes LCP Proximal Humerus Plate, cleared under K011815;

Synthes (USA), Synthes (USA) LCP® Proximal Humerus Plates, long, cleared under K041860; and

Exactech, Inc., Exactech® Equinoxe® Proximal Humerus Fracture Plate System, cleared under K093978.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate devices are all fabricated from the same or similar materials and share similar design characteristics. The subject and predicate devices encompass the same range of physical dimensions, are packaged using the same materials, and are to be sterilized by the same methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

Performance data provided to demonstrate substantial equivalence included detailed dimensional and engineering analysis of the subject and predicate devices, and fatigue testing of subject device and predicate device plate and screw constructs.

Overall, the APTUS Proximal Humerus System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principles,
- incorporates the same basic designs,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medartis AG
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APR 27 2012

Re: K120108
Trade/Device Name: APTUS® Proximal Humerus System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: April 23, 2012
Received: April 24, 2012

Dear Dr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120108

Device Name: APTUS® Proximal Humerus System

Indications for Use:

APTUS® Proximal Humerus System is indicated for fractures, osteotomies and non-unions of the proximal humerus.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120108